

Exhibit B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE COMMONWEALTH OF MASSACHUSETTS,)	
)	
Plaintiff,)	
)	
v.)	C.A. NO. 03-11865 PBS
)	
MYLAN LABORATORIES, INC., BARR)	
LABORATORIES, INC., DURAMED)	
PHARMACEUTICALS, INC., IVAX CORPORATION,)	
WARRICK PHARMACEUTICALS CORPORATION,)	
WATSON PHARMACEUTICALS, INC., SCHEIN)	
PHARMACEUTICAL, INC., TEVA)	
PHARMACEUTICALS USA, INC., PAR)	
PHARMACEUTICAL, INC., DEY, INC., ETHEX)	
CORPORATION, PUREPAC PHARMACEUTICAL CO.,)	
and ROXANE LABORATORIES, INC.)	
)	
Defendants.)	
)	

**PLAINTIFF COMMONWEALTH OF MASSACHUSETTS'S MEMORANDUM
IN SUPPORT OF ITS MOTION TO MODIFY PROTECTIVE ORDER TO
PERMIT SHARING OF DISCOVERY MATERIALS WITH OTHER STATE
AND FEDERAL LAW ENFORCEMENT PERSONNEL**

Introduction

The Plaintiff Commonwealth of Massachusetts (the "Commonwealth") hereby submits this memorandum in support of its Motion to Modify Protective Order to Permit Sharing of Discovery Materials With Other State and Federal Law Enforcement Personnel.

In the original protective order entered by the Court pursuant to a stipulation of the parties, this issue was identified but not resolved. Paragraph 3 of the current Order provides:

3. The parties are attempting to negotiate a stipulation regarding the right of the Commonwealth to share information covered by this protective order with other law enforcement officers who are not parties to this action. During these negotiations, the parties agree to be governed by the terms set forth below. If the parties are unable to reach an agreement on this matter, each party reserves the right to move this Court for further appropriate relief.

The parties have not been able to reach a further agreement on this issue. The only substantive¹ changes to the original Protective Order proposed here would add the following additional subparagraphs to paragraphs 5 and 7 respectively and a new paragraph 31 as follows:

5(k) Law enforcement officers of the states or the United States having responsibility for enforcement of the laws relating to Medicaid, Medicare and other federal and state statutes who have executed a certification in the form attached hereto as Exhibit A.

* * *

7(k) Law enforcement officers of the states or the United States having responsibility for enforcement of the laws relating to Medicaid, Medicare and other federal and state statutes who have executed a certification in the form attached hereto as Exhibit A.

31. Nothing contained in this Order shall prevent or in any way limit or impair the right of the Commonwealth to disclose to any agency or department of the United States, or any division of any such agency or department, or to any agency or department of any state or political subdivision thereof, CONFIDENTIAL information relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction, nor shall anything contained in this Order prevent or in any way limit or impair the use of any such CONFIDENTIAL information by a federal or state agency in any proceeding relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction; provided,

1. The proposed First Amended Protective Order also corrects four non-substantive typographical errors in the current order. These are the addition of a quotation mark in the fourth line of paragraph 16, correction of the date in the third line of Exhibit B, substitution of "for" in place of "or" in the sixth line of Exhibit B, and the addition of a close parenthesis in the fifth line of the third paragraph of Exhibit B.

however, that the agency shall maintain the confidentiality of
CONFIDENTIAL information consistent with the terms of this Order.

Background

The Medicaid Program is National in Scope and Cooperation Among Federal and State Participants is the Norm

The claims in this action all relate to overpayments for prescription drugs or underpayment of rebates in connection with the Commonwealth's Medicaid program. However, the issues underlying the claims are not unique to Massachusetts or Medicaid and are of vital interest to other federal and state healthcare law enforcement and administrative officials.

As this Court has recognized, "Medicaid is a unique 'system of cooperative federalism,' *Harris v. McRae*, 448 U.S. 297, 301, 100 S.Ct. 2671, 65 L.Ed.2d 784 (1980), where 'the two governments are pursuing common purposes.'" *Massachusetts v. Mylan Laboratories*, 357 F. Supp. 2d 314, 328 (D. Mass. 2005)(quoting *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666, 123 S.Ct. 1855, 155 L.Ed.2d 889 (2003)). See *Ark. Dep't of Health & Human Servs. v. Ahlborn*, --- U.S. ----, ----, 126 S.Ct. 1752, 1758, 164 L.Ed.2d 459 (2006) (describing Medicaid program as a "cooperative one" between the federal government and the states).

Medicaid is also a national program involving all states. While states are not required to participate in Medicaid, all of them do. *Ark. Dep't of Health & Human Servs. v. Ahlborn*, --- U.S. ----, ----, 126 S.Ct. 1752, 1758, 164 L.Ed.2d 459 (2006). The Federal Government pays between 50% and 83% of the costs a state incurs for patient care,² and,

2. The exact percentage of the federal contribution is calculated pursuant to a formula related to each State's per capita income. See 42 U.S.C. § 1396d(b); *Ark. Dep't of Health*

in return, the state pays its portion of the costs and complies with certain statutory requirements for making eligibility determinations, collecting and maintaining information, and administering the program. *Id.* See 42 U.S.C. §§ 1396a and 1396b.

Administration of Medicaid is assigned to the Secretary of Health and Human Services, who in turn exercises his authority through the Centers for Medicare and Medicaid Services (“CMS”) and the Office of the Inspector General (“OIG”). See *State of Montana v. Abbott Labs., Inc., et al.*, 266 F. Supp. 2d 250, 252 (D. Mass. 2003); *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 2006 WL 2563453, *1 (D. Mass. 2006). Under the statutes and regulations governing Medicaid, each state is required to develop a plan detailing standards for eligibility and the content of medical assistance it will provide. See generally 42 U.S.C. § 1396a(a). The Secretary “shall approve” any state plan which complies with the myriad requirements set forth in § 1396a(a) and (b). 42 U.S.C. § 1396a(b)(2006).

The Medicaid Statute and Regulations Require States to Cooperate With Each Other and the Federal Government in Medicaid Law Enforcement

While the statutory scheme affords the states a substantial amount of flexibility in how they administer their plans, there are also a number of specific requirements mandatory for all programs. For example, Congress requires each participating state to establish oversight programs and a Medicaid Fraud and Abuse Control Unit (“MFCU”) to identify and root out fraud and abuse in every aspect of Medicaid. 42 U.S.C. §§ 1396a(a)(30), (37), (61); §1396b(q). See *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 2006 WL 2563453, *3 (D. Mass. 2006). Because Medicaid

& Human Servs. v. Ahlborn, --- U.S. ----, ----, 126 S.Ct. 1752, 1758 n.3, 164 L.Ed.2d 459 (2006).

is a national program, law enforcement officials investigating Medicaid fraud with regard to any particular individual state's Medicaid program will often uncover problems or schemes that are present in other states' programs as well. Accordingly, the Medicaid statute also requires those state Medicaid fraud control units to cooperate with federal healthcare law enforcement personnel and their other state counterparts. Specifically, 42 U.S.C. §1396b(q), which sets out the standards for the states' Medicaid fraud control units, requires those units to report to the other appropriate law enforcement agencies any evidence of fraud in any federal health care program they become aware of in the course of their activities with regard to their own state plan. Subsection 1396b(q)(5) provides: "The entity [MFCU or equivalent] provides for the collection, *or referral for collection* to a single State agency, of overpayments that are made under the State plan *or under any Federal health care program . . .* that are discovered by the entity in carrying out its activities." 42 U.S.C. §1396b(q)(5)(2006)(emphasis added).

Similarly, the regulations of the U.S. Department of Health and Human Services, Office of the Inspector General, governing Medicaid fraud control units require each state unit to "make available to Federal investigators or prosecutors all information in its possession concerning fraud in the provision or administration of medical assistance under the State plan and will cooperate with such officials in coordinating any Federal and State investigations or prosecutions involving the same suspects or allegations." 42 C.F.R. §1007.11(e)(2006).

State and Federal Law Enforcement Officials Routinely Cooperate in Medicaid Enforcement

As part of these mandated cooperative efforts, the Commonwealth of Massachusetts, along with 48 other states and the District of Columbia, is a participating member of the National Association of Medicaid Fraud Control Units (“NAMFCU”), whose mission is to cooperate in the investigation and prosecution of Medicaid fraud. NAMFCU serves as a forum for the nationwide sharing of information with law enforcement officials charged with Medicaid fraud control. It works to foster interstate cooperation on law enforcement and federal issues affecting the MFCU of each state. During fiscal year 2005, the state MFCUs collectively recovered \$709 million in court-ordered fines, civil settlements and penalties and obtained 1123 convictions. *See State Medicaid Fraud Control Units Annual Report Fiscal Year 2005, Department of Health and Human Services, Office of Inspector General at*
<http://www.oig.hhs.gov/publications/docs/mfcu/MFCU%202004-5.pdf>. Many of the investigations that resulted in these recoveries were also conducted in cooperation with federal law enforcement agencies.

Current Status of Discovery

The parties are currently in the process of exchanging documents. No depositions have been taken as yet.

Legal Standard for Issuing a Protective Order:

The standard for issuance of any discovery protective order, and the standard applicable to maintenance of the existing Protective Order in this case, is set forth in Rule 26(c). The rule provides that “[u]pon motion by a party . . . and *for good cause shown*, the court . . . may make any order which justice requires to protect a party or person from

annoyance, embarrassment, oppression, or undue burden or expense, including . . . (7) that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way" Fed.R.Civ.P. 26(c) (emphasis added).

Defendants, as the parties seeking protection, bear the burden of proving "good cause" by demonstrating a factual basis of potential harm. Fed.R.Civ.P. 26(c)(7). See *Anderson v. Cryovac, Inc.*, 805 F.2d 1, 7 (1st Cir. 1986); *Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775, 789 (1st Cir. 1988). For good cause to exist, the party seeking protection must demonstrate that specific prejudice or harm will result if no protective order is granted. *Anderson v. Cryovac, Inc.*, 805 F.2d at 7; *Prozina Shipping Co., Ltd. v. Thirty-Four Automobiles*, 179 F.R.D. 41, 48 (D. Mass. 1998). See *Beckman Indus., v. International Ins. Co.*, 966 F.2d 470, 476 (9th Cir. 1992) (holding that "broad allegations of harm, unsubstantiated by specific examples or articulated reasoning, do not satisfy the Rule 26(c) test."). See also *San Jose Mercury News, Inc.*, 187 F.3d 1096, 1102 (9th Cir. 1999) (holding that to gain a protective order the party must make a "particularized showing of good cause with respect to any individual document").

If good cause is not shown, the discovery materials in question should not receive judicial protection and therefore should be open to the public for inspection. *Public Citizen v. Liggett Group, Inc.*, 858 F.2d at 789. Any other conclusion effectively would negate the good cause requirement of Rule 26(c). *Id.*; *Mangosoft, Inc. v. Oracle Corp.*, 2005 WL 2203171, *2 (D.N.H. 2005). Because a protective orders limits the extent to which disclosure is made, the relevant injury to be weighed in the balance is not the injury that would be caused by public disclosure, but the injury that would result from the

scope of disclosure permitted under the proposed protective order. *Coca-Cola Bottling Co. of Shreveport, Inc. v. Coca-Cola Co.*, 107 F.R.D. 288, 293 (D. Del. 1985). A necessary corollary to the “good cause” rule is that the scope of the protective order should be no broader than the scope of the good cause shown to exist. To the extent that good cause is not shown for precluding disclosure to any particular group, the scope of the order should not include that group.

ARGUMENT

I. BECAUSE MEDICAID FRAUD CONTROL UNITS ARE REQUIRED BY FEDERAL STATUTE AND REGULATION TO REPORT EVIDENCE OF FRAUD THEY DISCOVER IN ANY FEDERAL HEALTH CARE PROGRAM, ANY PROTECTIVE ORDER IN THIS ACTION SHOULD NOT RESTRICT SUCH REPORTING

As discussed above, the federal Medicaid statute requires each Medicaid fraud and abuse control unit to report to other law enforcement officials evidence of fraud or overpayments “*under any Federal health care program . . .* that are discovered by the entity in carrying out its activities.” 42 U.S.C. §1396b(q)(5)(2006)(emphasis added). Similarly, the regulations of the U.S. Department of Health and Human Services, Office of the Inspector General, governing Medicaid fraud control units require each state unit to “make available to Federal investigators or prosecutors all information in its possession concerning fraud in the provision or administration of medical assistance under the State plan and will cooperate with such officials in coordinating any Federal and State investigations or prosecutions involving the same suspects or allegations.” 42 C.F.R. § 1007.11 (e). There is no limitation of this requirement to investigations outside the civil litigation context.

This litigation is a perfect example of just such a type of national problem contemplated by the enforcement coordination provisions of the Medicaid statute and regulations. Drug pricing fraud based on inflation of reported prices affects every one of the 50 state Medicaid programs and Medicare. When one Medicaid fraud control unit uncovers evidence of fraud on a national basis, it has an obligation to alert other states and the federal government to the problem and to share with them the evidence it uncovers that affects them. Accordingly, any protective order entered by the Court and applicable to the Commonwealth's Medicaid Fraud Control Unit in this action should not restrict such cooperation in any manner inconsistent with these statutory and regulatory obligations.

II. THE DEFENDANTS HAVE NO LEGALLY PROTECTED INTEREST IN PRECLUDING OTHER STATE AND FEDERAL LAW ENFORCEMENT OFFICIALS FROM RECEIVING INFORMATION DISCLOSED IN DISCOVERY

The principal purpose of a protective order governing trade secrets and other confidential business information is to prevent unauthorized disclosure of the materials to competitors and others who might use the information to obtain a competitive advantage. In this case, the Commonwealth agrees that there is likely good cause to protect certain of the defendants' business data, such as some current pricing data, from such public disclosures. For this reason, the Commonwealth has agreed to the current Protective Order that generally restricts disclosures of such information to the general public and contains additional restrictions to prevent disclosures to competitors.

However, there is no justification for precluding other officials responsible for enforcement of health care laws from receiving information concerning the defendants' interactions with Medicaid programs and provision of prescription drugs to Medicaid

providers. First, concealing evidence of illegal conduct from law enforcement authorities and “the naked desire to avoid prosecution” are not “good cause” to justify a protective order. *U.S. v. Talco Contractors, Inc.*, 153 F.R.D. 501, 515 (W.D. N.Y. 1994); *Chemical Bank v. Affiliated FM Insurance Company*, 154 F.R.D. 91, 94 (S.D. N.Y. 1994). To the contrary, disclosure of discovery materials is generally in the public interest because it “often exposes the need for governmental action or correction.” *Sharjah Investment Company (UK), Ltd v. P.C. Telemart, Inc.*, 107 F.R.D. 81, 83 n. 1 (holding that a protective order entered by stipulation could not preclude disclosure of a deposition transcript to the Securities and Exchange Commission and quoting *Chicago Council of Lawyers v. Bauer*, 522 F.2d 242, 258 (7th Cir. 1975)). In *Chicago Council of Lawyers*, the Court struck down restrictions on lawyers’ public comments on pending civil litigation in part because of the public policy against non-disclosure of “the need for governmental action or correction” that is often disclosed in civil litigation. *Id.*

Second, there is no information belonging to any of the defendants that is relevant to the litigation and must be disclosed to the Commonwealth that could not be obtained by every other state’s Medicaid Fraud Control Unit under the Medicaid statute. Accordingly, the only interest being served by a protective order that precludes sharing such information is the defendants’ interest in requiring all 50 states to expend the time, effort and scarce resources to uncover the fraud independently. Again, such an interest is not “good cause” for purposes of Rule 26(c) and is not consistent with Rule 1 of the Federal Rules of Civil Procedure, providing for the “just, speedy, and inexpensive determination of every action.” The Commonwealth’s sharing of discovery with other states and the federal government will save time and money and impose less of a burden

on the parties involved, including the states having limited resources. In investigating and prosecuting essentially the same claims of overcharging Medicaid through falsely inflated pricing, the states would not have to re-subpoena the already-conducted discovery. Such sharing would also be consistent with the procedures for such sharing adopted by other courts. *See, e.g.*, Exhibit 1, Transcript of Motion Hearing before the Honorable L. Ralph Smith at 37, 42, *State of Florida ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim, Corp., et al.*, Case No. 98-3032A (Fla. Cir. Ct. July 19, 2004)(in ruling that the State of Florida could share discovery with other law enforcement officials, including officials of the federal and other state governments, Judge Smith stated that “the information ought to be available to the government to share with other government agencies who have the right to get the same type of information as long as that attorney general or law enforcement agency will agree to the restrictions [in the protective order]”). *Id.* at 42.

Third, and most obviously, law enforcement officials of federal and state governments are not “competitors” of the defendants. Such officials’ use of the information solely for law enforcement purposes does not implicate any of the issues of unfair competition that are the rationale for protecting confidential and proprietary business information.

In this case, the Commonwealth fully expects that discovery will further support its claims that the defendants defrauded the Massachusetts Medicaid program. The same evidence will likely support similar claims for other Medicaid programs and support prosecution of those claims by both federal and state authorities. There is no reason that

such evidence should not be made available to law enforcement officials responsible for policing the Medicaid programs in the Commonwealth's sister states.

CONCLUSION

For the foregoing reasons, the Commonwealth's Motion to Modify Protective Order to Permit Sharing of Discovery Materials With Other State and Federal Law Enforcement Personnel should be allowed.

Respectfully submitted,

COMMONWEALTH OF MASSACHUSETTS
By its attorney,

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November 21, 2006

CERTIFICATE OF SERVICE

I hereby certify that on November 21, 2006, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic means through the Court's ECF filing system.

/s/ Richard C. Heidlage